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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of inventor Saraf
Serial No. 09/870,986 Group Art Unit: 1634
Filed: 06/01/2001 Examiner: Chakrabarti

For: ***"BIO-CHIP, PHOTOLUMINESCENT METHODS FOR IDENTIFYING BIOLOGICAL MATERIAL, AND APPARATUS FOR USE WITH SUCH METHODS AND BIO-CHIPS"***

Assistant Commissioner for Patents
Washington, D.C. 20231

REQUEST FOR CONTINUED EXAMINATION AND AMENDMENT UNDER 37 CFR 1.114

Dear Sir:

In response to the Final Office Action mailed on 06/17/2002, Applicant herewith submits a Request for Continued Examination, and an amendment of the patent application as follows:

IN THE CLAIMS:

Please amend the following claims: 1 and 20. A clean copy of the amended claims is attached.

1. (Twice amended) A tagging-free method to detect the binding of an untagged single stranded nucleic acid sequence to an untagged material of interest [molecules], comprising the steps of:

(A) providing a sensor comprised of a first layer and a second layer wherein said first layer comprises [a] an untagged single stranded nucleic acid sequence and wherein said second layer comprises a photoluminescent material, and wherein said first layer and said second layer are separate layers;

(B) exposing said sensor to a biological sample for sufficient time for said untagged single stranded nucleic acid sequence to bind to [a] an untagged material of interest in said biological sample;

(C) applying light to said sensor; and

(D) measuring photoluminescence from said sensor, wherein photoluminescence measured in said step of exposing is indicative of binding of [molecules] said untagged single stranded nucleic acid sequence to said untagged material of interest .

20 (Twice amended). The tagging-free method of claim 1, wherein said first layer comprises a plurality of sections each of which comprises a different untagged single stranded nucleic acid sequence.

REMARKS

The application includes claims 1-23, which represent Applicant's previous election, without traverse, of the "Group I" claims. Claims 1 and 20 are hereby amended.

Applicant thanks Examiner for the courtesy extended to Applicant's representative during the interview of July 8, 2002, and for the indication that the proposed amendment to claim 1 would be considered favorably over the prior art currently of record. Applicant notes that the term "untagged" has been substituted for the term "unlabeled" in the proposed amendment presented at the interview because the term "untagged" was utilized repeatedly in the specification. Applicant submits that the two terms are used interchangeably in the art.

35 U.S.C. §103(a) rejection

Examiner's Point #3

Claims 1-5, 7, 13-17 and 19-20 stand rejected under U.S.C. 35 §103 over Leland et al. (US Patent 5,962,218) in view of Charra (US Patent 5,831,259).

Leland et al. teaches a method for performing a binding assay for an analyte of interest. The assay is based on the detection of electrochemiluminescence. However, as stated by Examiner, Leland et al. do not teach a tagging-free method. In fact, the method of Leland et al.

has an absolute requirement for tagging or labeling of the "assay-performance-substance", the term utilized by Leland et al. to describe the molecule or molecular complex which binds the analyte of interest.

Applicant notes that the method of Leland et al. further requires the use of "a plurality of inanimate *particles*" (emphasis mine) which in some cases are magnetic particles. (See claim 1, line 50; claim 4, line 50; claim 5, line 13; claim 16, line 11; claim 21, line 50; claim 26, line 22; claim 29, line 59; claim 45, line 58; and column 12, lines 20-35). As such, the invention of Leland et al. is not a "bio-chip" type detection device and the invention of Leland et al. cannot be equated with the present invention, which has no such requirement. Further, there is no suggestion or showing in Leland et al. that a tagging free adaptation of the method of Leland et al. would be either possible or desirable.

Examiner asserts that Charra teaches a tagging free method, providing a first layer of oligomer and a second layer of photoluminescent material which consists of aromatic polymers embedded in the matrix material, and that a combination of Charra with Leland et al. would be possible and would result in the method of the present invention. However, since Leland et al. as described above is limited to an assay based on a plurality of particles, a combination of Leland et al. and Charra would not result in a biochip as described in the present invention.

Further, claim 1 and claim 20 have hereby been amended to recite that the method involves the use of untaggged material, in sharp contrast to Leland et al.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Examiner's Point #4. Claims 1-7, 11-17 and 19-20 stand rejected over Leland et al in view of Charra and further in view of Leising et al.

Examiner states that Leising et al. supply the teaching of a matrix layer comprising polystyrene. However, this is a moot point since, as shown above, the combination of Leland et al. and Charra does not result in the method of the present invention.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully

requested.

Examiner's Point #5. Claims 1-5 and 7-23 stand rejected over Leland et al. in view of Charra and further in view of Bhargava et al.

Examiner states that Bhargava et al. further supplies the teaching of utilizing doped or undoped zinc sulfide, and the use of ultraviolet light with a "wavelength in the range of 200-700nm". However, as discussed above, there is no reasonable combination of Leland et al. and Charra with which to combine Bhargava et al., thus the teaching of Bhargava et al. is moot.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Examiner's Point #7.

Examiner states that the "features upon which applicant relies (i.e. no extrinsic tagging or labeling of the molecules which undergo binding is necessary in order to detect bound molecules and first layer and second layer of the claimed invention are separate) are not recited in the rejected claim(s)." Claim 1 of the application has hereby been amended to recite that:

1) the single stranded nucleic acid of the sensor is untagged and the material of interest to which the ss nucleic acid binds is also untagged; and

2) the first layer (which contains the ss nucleic acid) and said second layer (which contains the photoluminescent material) are separate layers.

Likewise, claim 20 has been amended to recite that the different nucleic acid sequences described therein are untagged.

Support for these amendments is found in the specification at several locations, including:
1) inclusion of "untagged": in the summary, on page 3 and line 10, which states "...without needing to tag the sample"; page 8, lines 7-13, where reference is made to "nucleic acid...or protein sequence analysis without tagging" and "without using conventional tagging".
2) inclusion of "separate layers": in the summary, page 3, lines 20-31 and page 3, lines 1-7, which describe distinct first and second layers in detail.

Applicant submits that these amendments make clear the distinctions between the present invention and the methodology of the references cited by the Examiner.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Formal Matters and Conclusion

In view of the foregoing, Applicant submits that all rejections have been successfully traversed. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a telephonic or personal interview.

Please charge any underpayment or credit any overpayment of fees to attorney's deposit account #50-2041.

Respectfully submitted,

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703-787-9400